

Frank A. Nelson, Chicago, Ill., a number of tubes of *Interferin* which were misbranded, and that the defendant subsequently sold a number of the tubes in violation of Section 301 (c).

**PRODUCT:** Unlabeled collapsible tubes containing an amber-colored paste, known as *Interferin*, intended for introduction into the uterine cavity for the purpose of terminating pregnancy.

**NATURE OF CHARGE:** Misbranding, Section 502 (b) (1) and (2), the product was in package form and failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of the contents; Section 502 (e) (2), the label failed to bear the common or usual name of each active ingredient; and, Section 502 (f) (1), it failed to bear adequate directions for use.

**DISPOSITION:** August 14, 1946. A plea of guilty having been entered, the court imposed a fine of \$1,000.

**1957. Misbranding of Chinaroid Rectal Balm. U. S. v. The Knox Co. Plea of nolo contendere. Fine, \$500. (F. D. C. No. 16543. Sample No. 39536-F.)**

**INFORMATION FILED:** October 29, 1945, Western District of New York, against the Knox Co., a corporation, Buffalo, N. Y.

**ALLEGED SHIPMENT:** On or about October 9, 1943, from the State of New York into the State of California.

**PRODUCT:** This product was an ointment in a collapsible tube with a key attachment. The directions called for a "one-quarter turn" of the key. At the start, one-quarter turn would cause an application of ointment containing 0.444 gram of stramonium. As the tube rolled up, the amount would increase until, at the maximum, the one-quarter turn would cause an application of ointment containing 5.056 grams of stramonium.

**NATURE OF CHARGE:** Misbranding, Section 502 (a), the labeling of the drug was misleading since it failed to reveal the material fact that the use of the article in accordance with the following directions on the label might have resulted in an overdosage of stramonium, and that an overdosage of stramonium may be dangerous: "Use Twice Daily Attach key to bottom of tube and turn slightly until salve reaches end of applicator and exudes. Insert applicator gently into rectum and turn key, attached to tube, one-quarter turn. This provides the proper dose of Chinaroid. If bleeding exists apply Chinaroid with finger instead of inserting applicator. Repeat morning and night as needed to relieve rectal discomfort. If satisfactory relief is not obtained after using for 2 weeks consult a physician."

Further misbranding, Section 502 (f) (1), the labeling failed to bear adequate directions for use since the directions would provide for the administration of an amount of ointment varying from 0.444 gram to 5.056 grams, which might have resulted in a dangerous overdosage of stramonium; and, Section 502 (f) (2), the label failed to bear adequate warnings against unsafe dosage, or methods or duration of administration or application, since it failed to warn that the dosage should be decreased if blurring of the vision or dryness of the throat should develop, and it failed to warn that if those conditions persisted after decreasing the dosage, use of the article should be discontinued. The labeling failed also to warn against use of the drug in those pathological conditions where its use might have been dangerous to health, since it failed to warn that the article should not be used in case of bleeding, which warning is necessary in the case of drugs intended for introduction into the rectum.

**DISPOSITION:** January 28, 1946. A plea of nolo contendere having been entered on behalf of the defendant, a fine of \$500 was imposed.

**1958. Misbranding of Improved Special Tablets. U. S. v. 34 Bottles of Improved Special Tablets. Default decree of condemnation and destruction. (F. D. C. No. 20277. Sample No. 57040-H.)**

**LIBEL FILED:** June 20, 1946, District of Massachusetts.

**ALLEGED SHIPMENT:** On or about April 30, 1946, by M. A. Williams, Inc., from Woonsocket, R. I.

**PRODUCT:** 34 bottles, each containing 24 *Improved Special Tablets*, at Boston, Mass.

**LABEL, IN PART:** "Improved Special 24 Tablets."

**NATURE OF CHARGE:** Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use since it failed to state why the article was to be used.

**DISPOSITION:** August 6, 1946. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

**1959. Misbranding of W-Whey. U. S. v. 23 Packages and 8 Packages of W-Whey. Default decree of condemnation and destruction. (F. D. C. No. 19688. Sample Nos. 50681-H, 50682-H, 50684-H.)**

**LIBEL FILED:** April 26, 1946, Southern District of Iowa.

**ALLEGED SHIPMENT:** On or about February 5, 1946, by Schiff Bio-Food Products, from Detroit, Mich.

**PRODUCT:** 23 12-ounce packages and 8 30-ounce packages of *W-Whey* at Davenport, Iowa. Federal Health Foods, Davenport, Iowa, purchased from the publishers and distributed to its mailing list approximately 2,000 copies of a booklet entitled "Federal's Health News." On page 17 of this magazine was an advertisement sponsored by the packer of the product, for "Little Miss Muffet Brand W-Whey," in which the article is offered for bad breath, coated tongue, tired, haggard looks, excessive food decomposition, bowel gas, irritability, headaches, sallow skin, and poor appetite.

Examination showed that the product was dried whey containing, per ounce, compounds of calcium equivalent to not more than 171 milligrams of calcium, and compounds of phosphorus equivalent to not more than 187 milligrams of phosphorus.

**LABEL, IN PART:** "Little Miss Muffet Brand W-Whey Schiff's Whole Powdered Milk Whey."

**NATURE OF CHARGE:** Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use of the product in the treatment of bad breath, coated tongue, tired, haggard looks, excessive food decomposition, bowel gas, irritability, headaches, sallow skin, and poor appetite, which are the conditions for which the article was offered in its advertising sponsored by or on behalf of its manufacturer, packer, or distributor.

The article was alleged to be misbranded also under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

**DISPOSITION:** July 16, 1946. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

**1960. Misbranding of Trexcene Special Tablet Compound. U. S. v. 3,350 Boxes of Trexcene Special Tablet Compound. Default decree of condemnation and destruction. (F. D. C. No. 20230. Sample No. 63247-H.)**

**LIBEL FILED:** June 11, 1946, Southern District of New York.

**ALLEGED SHIPMENT:** On or about April 22, 1946, by the Ivers Lee Co., Newark, N. J.

**PRODUCT:** 3,350 boxes, each containing 24 tablets, of *Trexcene Special Tablet Compound* at New York, N. Y. Examination showed that the product consisted essentially of a laxative plant drug such as aloes, iron sulfate, oil of pennyroyal, and extracts from plant materials, and that it was coated with calcium carbonate and sugar.

**NATURE OF CHARGE:** Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use, since it failed to state why the article was to be used; and, Section 502 (f) (2), it failed to bear adequate warnings against use in those pathological conditions where its use may be dangerous to health, and against unsafe duration of administration, since the article was essentially a laxative. In addition, the label statement "Not for use in pregnancy or appendicitis" would not inform users that the article should not be taken in case of nausea, vomiting, abdominal pain, or other symptoms of appendicitis, and it failed to warn that frequent or continued use of the article might result in dependence upon laxatives.

**DISPOSITION:** July 26, 1946. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

**1961. Misbranding of Glando-Plex Tablets. U. S. v. 60 Bottles of Glando-Plex. Default decree of condemnation and destruction. (F. D. C. No. 16685. Sample No. 23606-H.)**

**LIBEL FILED:** July 5, 1946, Western District of Texas.

**ALLEGED SHIPMENT:** On or about March 20 and April 1, 1945, by the Veltex Co., from Birmingham, Ala.